REMARKS

Claims 37-50 and 52-72 are pending, wherein claims 37, 56 and 71 have been amended, claim 51 was cancelled, and new claim 72 was added in order for Applicant to more fully claim what he regards as his invention. Reconsideration and allowance for the above-identified application are now respectfully requested in view of the foregoing amendments and the following remarks.

As discussed in previous amendments, the inventive methods utilize highly penetrating compositions that can penetrate into disordered tissue and kill viruses, bacteria and/or fungus after only one or two applications. *See* Application, page 45, lines 14-21 (describing two exemplary application processes: (i) a first exemplary process in which all the treatment composition is applied over a period of 30 seconds or longer and (ii) a second exemplary process in which half of the composition is applied in one application and the other half in a second application over a period of about 2 minutes)[1].

The ability to effectively kill viruses, bacteria and/or fungus and treat disordered tissue in only one or two applications is surprising, unexpected and unpredictable in view of the teaching in Beauchamp et al. (US 5,753,270) that the treatment compositions disclosed therein must be applied to herpes infections repeatedly and often over a long period of time each day and over multiple days to be effective:

> Directions (Treatment for Herpes Simplex I and II)
>
> 1. Apply liberally to the afflicted area ***3 to 4 times*** over a one minute time period. ***Repeat every 3 minutes over a 10 minute period***.
> 2. ***Repeat above procedure*** after approximately 1/2 to 1 hour.
> 3. To ensure virus activity is stopped ***repeat application*** as prescribed in initial treatment ***every 2 to 3 hours*** or until activity is stopped and healing is evident.
> 4. To hasten healing apply ***2 to 3 applications twice daily***.

Col. 5, lines 55-65 (emphasis added).

[1] To the extent the second exemplary process involves dispensing all the treatment composition from a single use container, such as the frangible single use container illustrated in Figures 2A-2E, over a relative short period of time (*e.g.*, 2 minutes or less), the two-step process may be considered to constitute a single application step.

Applicant acknowledges that applying the composition "liberally to the afflicted area 3 to 4 times over a one minute time period" in step 1 can and should be considered to be a single application. Even so, Beauchamp et al. teaches *four* of such applications "over a 10 minute period" (*i.e.*, 3 or 4 times during each of the 1st minute, 4th minute, 7th minute, and 10th minute) in step 1. In step 2, Beauchamp et al. says to repeat the procedure in step 1 after approximately ½ to 1 hour, for a total of *eight* applications so far. In step 3, Beauchamp et al. says to repeat the application "as prescribed" (*i.e.*, in steps 1 and 2) "every 2 to 3 hours". If the procedure of steps 1 and 2 is repeated only once in step 3, the total number of applications according to Beauchamp et al. becomes *sixteen*. If, according to optional step 4, the procedure of steps 1 and 2 is repeated 2 to 3 times "twice daily", the total number of applications according to Beauchamp et al. becomes *thirty-two* or *forty-eight* every half day, or 64 to 96 applications per day. Thus, Beauchamp et al. discloses a truly onerous treatment regimen that would be very difficult, time consuming, and tedious to follow. From the foregoing teachings of Beauchamp et al., one of ordinary skill in the art would not expect the treatment composition as recited in the method claims of the present application to be effective in killing viruses, bacteria and/or fungus after only one or two applications to the disordered tissue.

I. REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Office Action states that claim 71 is rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the act of "identifying disordered tissue caused by a virus ... is a concept that was not present in the specification as originally filed." The Office Action further states that treating disordered tissues caused by viruses, bacteria or fungus is not the same thing as "identifying" such disordered tissues. In response, Applicants note that the act of identifying disordered tissues is inherent in the teaching that the treatment compositions were selectively applied to disordered tissues. It would be impossible to selectively apply a treatment composition to a disordered tissue without first identifying it (*i.e.*, determining where on the body it is located). Indeed, identifying disordered tissue is often as simple as seeing where the lesions are on the body. For example, cold sores, genital herpes lesions, chicken pox, smallpox, and shingles are all caused by a virus, are readily visible, and therefore require little or no effort to "identify". A cold sore is often an "open sore". Application, page 16, lines 12-13. If a cold sore is not yet visible, the Application teaches that the patient will usually experience a "tingling and tightening sensation". Application, page 60, lines 2-4. This is yet another way to "identify"

disordered tissue caused by a virus. Figures 8-12 illustrate the application of a treatment composition to visibly apparent disordered tissues on various parts of the body. This supports the view that "identifying" such disordered tissues can be as easy seeing lesions or sores on the body. The examples set forth at pages 60-70 of the Application disclose numerous instances in which patients were "diagnosed" as having cold sores or other disordered tissues. Such diagnosis falls within the meaning of "identifying" cold sores or other disordered tissues caused by a virus, bacteria and/or fungus. Accordingly, Applicants submit that claim 71 as previously presented fully complied with the requirements of 35 U.S.C. § 112, first paragraph, relative to written description.

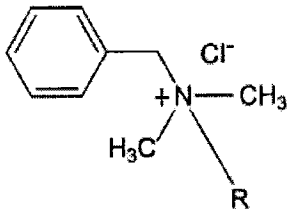
Notwithstanding the foregoing, and in an effort to advance prosecution, Applicant amended independent claims 37 and 71 to change "*identifying* disordered tissue" to --*providing* disordered tissue--. Each of the patients that were treated in the examples, as well all instances in which disordered tissues are treated, "provided" the disordered tissue (*i.e.*, it was presented and then treated). In view of the foregoing, Applicant respectfully requests withdrawal of all rejections under 35 U.S.C. § 112, first paragraph.

II. ART REJECTIONS

The Office Action rejects claims 37-47 and 53-71 under 35 U.S.C. § 103(a) as being unpatentable over Beauchamp et al. and Remington's Pharmaceutical Sciences, 1975 ("Remington"). In response, Applicant submits that the claims as now presented are unobvious over the combination of Beauchamp et al. and Remington, either alone or if combined with any other art of record.

Claim 1 as amended claims a method for locally treating pathogen-induced disordered tissue caused by at least one of a virus, a bacteria, or a fungus, comprising: providing disordered tissue caused by a virus, bacteria or fungus; and applying a treatment composition to the disordered tissue so as to form a reservoir of the treatment composition within the disordered tissue and so that the treatment composition kills at least one of viruses, bacteria or fungus before diffusing beyond the disordered tissue. Claim 1 further specifies that "the treatment composition [is] effective in killing at least of viruses, bacteria or fungus after only one or two applications of the treatment composition to the disordered tissue". *See* Application, page 45, lines 14-21. Claim 1 further specifies that the treatment composition comprises at least one organohalide compound in a liquid carrier that includes a tissue penetrating agent for penetrating skin and the

disordered tissue, the at least one organohalide compound comprising one or more of n-dialkyl methyl benzyl ammonium halide, n-alkyl dimethyl ethylbenzyl ammonium halide, a quaternary ammonium halide having an ammonium nitrogen and an alkyl radical with six to eighteen carbons bonded to the ammonium nitrogen, or benzalkonium chloride having the following chemical structure:



wherein R is an alkyl group having 8-18 carbons.

The combination of Beauchamp et al. and Remington fails to disclose or suggest the combination of elements recited in claim 37 as now presented. For example, Beauchamp et al. fails to disclose or suggest a treatment composition and a method of using the treatment composition in which "the treatment composition [is] effective in killing at least of viruses, bacteria or fungus after only one application of the treatment composition to the disordered tissue". Instead, as quoted and discussed above, Beauchamp et al. teaches a composition that, when used to treat Herpes Simplex I and II, must be applied numerous times throughout the day to be effective (*i.e.*, at least 16 times per day, up to 64 to 96 times per day). *See* Beauchamp et al., col. 5, lines 55-65. As Remington was only cited for the narrow teaching of massaging an unspecified treatment composition into hair follicles, Remington fails to cure the deficiencies of Beauchamp et al. There is nothing in Remington that would suggest to the skilled artisan how to modify the treatment composition of Beauchamp et al. in order for it to be "effective in killing at least of viruses, bacteria or fungus *after only one application* of the treatment composition to the disordered tissue". For this reason alone, Applicant submits that claim 37 as now presented is patentable over the art of record.

Claims 38-50 and 52-70 depend from claim 37 and are therefore patentable over the art for at least those reasons given above relative to claim 37. In addition, they recite additional elements that may further distinguish over the applied art. For example, claim 38 further claims "the disordered tissue comprising stratum corneum and stratum spinosum, the treatment composition being applied to the disordered tissue so that the treatment composition penetrates through the stratum corneum and forms the reservoir of treatment composition within the stratum

spinosum of the disordered tissue". Applicant submits that, because Beauchamp et al. requires the disclosed composition to be applied repeatedly throughout the day, one of skill in the art would not interpret Beauchamp et al. as actually or inherently disclosing a method in which "the treatment composition penetrates through the stratum corneum and forms the reservoir of treatment composition within the stratum spinosum of the disordered tissue". In rejecting claim 38, the Office Action cites to column 3, lines 28-34 of Beauchamp et al. However, this portion of Beauchamp et al. merely states that the composition merely penetrates "into the skin", not "through the stratum corneum" so as to form a "reservoir of treatment composition within the stratum spinosum of the disordered tissue". Nor would this obviously or inherently occur when employing the disclosed composition and application methods of Remington. For this additional reason, Applicant submits that claim 38 is patentable over the applied art.

Claim 42 further claims "the treatment composition being applied while *firmly compressing the disordered tissue* against at least one of bone, tooth, gum, or other tissue underlying the disordered tissue in order to assist penetration of the treatment composition into the disordered tissue". Neither Beauchamp et al. nor Remington discloses or suggests any such application method.

Claim 44 further claims "the applicator having a flat tissue contacting surface that assists in causing the treatment composition to penetrate into the disordered tissue". Neither Beauchamp et al. nor Remington discloses or suggests the use of an applicator having the specific structure recited in claim 44 for any reason, much less to apply a treatment composition to disordered tissue.

Claim 45 further claims "the applicator having a tissue contacting surface with a size in a range of about 50% to about 200% of the size of the disordered tissue". Neither Beauchamp et al. nor Remington discloses or suggests the use of an applicator having the specific structure recited in claim 45 for applying a treatment composition to disordered tissue.

Claim 47 further claims "the treatment composition being applied to the disordered tissue using a towellete". Neither Beauchamp et al. nor Remington discloses or suggests the use of an applicator having the specific structure recited in claim 47 for any reason, let alone for applying a treatment composition to disordered tissue.

Claims 48-50 and 52 further specify certain compositional characteristics that are neither taught nor suggested by Beauchamp et al. or Remington.

Claim 53 further claims "wherein the treatment composition is formulated and applied so as to be no longer visibly detectable on the disordered tissue within about two minutes after application of the treatment composition onto the disordered tissue". The Office Action acknowledges that Beauchamp et al. does not disclose a method in which the composition is no longer visible after about two minutes but alleges that the isopropyl alcohol is volatile and will quickly evaporate and no longer be visible. However, the composition Beauchamp et al. includes non-volatile oils as well, including menthol, thymol and eucalyptol (*e.g.*, col. 5, lines 44-46), which would likely leave an oily residue on the skin after two minutes. Moreover, the exemplary composition includes iodine, which is known to stain skin and therefore remain highly visible.

Claim 54 further claims "wherein the treatment composition leaves no significant residue on a surface of the disordered tissue after penetrating into the disordered tissue". Applicants submit that slow penetrating oils such as menthol, thymol and eucalyptol will leave a significant residue on the skin.

Claim 55 further claims "wherein the at least one organohalide compound is comprised of benzalkonium chloride having an n-alkyl chain length that is at least one of C_{12}, C_{14}, C_{16}, or C_{18}". While Beauchamp et al. discloses quaternary ammonium compounds, including benzethonium chloride, Beauchamp et al. fails to disclose or suggest the use of the specific type of benzalkonium chloride compound recited in claim 55.

Claim 61 further claims "wherein the liquid carrier comprises isopropyl alcohol and water, the isopropyl alcohol being in an amount ranging form about 60% to about 80% by volume of the liquid carrier". While Beauchamp et al. discloses the use of isopropyl alcohol and water, Beauchamp et al. fails to disclose or suggest the specific concentration range recited in claim 61, which has been found to be particularly effective in promoting rapid penetration of the treatment composition.

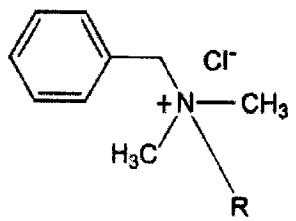
Claim 62 more specifically claims "wherein the liquid carrier comprises an aqueous solution of isopropyl alcohol at a concentration of about 70% of isopropyl alcohol by volume of the carrier", thus further distinguishing over the applied art.

Claim 65 further claims "the disordered tissue comprising at least one lesion caused by smallpox virus". Because smallpox is a much more virulent and fatal disease than herpes simplex, there is no reasonable expectation that the composition of Beauchamp et al. would be effective in treating smallpox. Moreover, there is no teaching, suggestion, motivation or other

reason that would have prompted the skilled artisan to modify the composition of Beauchamp et al. in a manner that would render it effective in treating smallpox. A similar argument applies to claim 66, which claims treating at least one lesion caused by anthrax bacteria.

Claim 68 further claims "wherein the disordered tissue is located on a person's genitalia, the treatment composition being applied to the disordered tissue on the person's genitalia". There is currently no commercial product of which the undersigned is aware that is designed to be topically applied to genital herpes or other genital disordered tissues. Accordingly, there is no reasonable expectation that the composition of Beauchamp et al. would be useful in treating genital herpes or other genital disordered tissues.

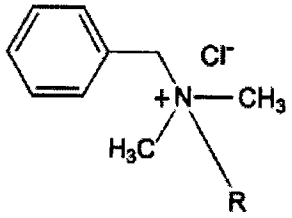
Independent claim 71 alternatively claims a method for locally treating pathogen-induced disordered tissue caused by at least one of a virus, a bacteria, or a fungus, comprising: providing disordered tissue caused by a virus; and applying a treatment composition to the disordered tissue so as to form a reservoir of the treatment composition within the disordered tissue and so that the treatment composition kills at least one of viruses, bacteria or fungus before diffusing beyond the disordered tissue. The treatment composition is applied to the disordered tissue to form the reservoir of the treatment composition within the disordered tissue and so that the treatment composition kills at least one of viruses, bacteria or fungus before diffusing beyond the disordered tissue according to at least one of: (i) applying the treatment composition in only one application (Application, page 45, lines 14-21); (ii) applying the treatment composition in one or more applications over a maximum period of about two minutes (Application, page 45, lines 14-21); or (iii) applying the treatment composition in one or more applications from a single use container (Application, page 38, lines 22-23). The treatment composition comprises at least one organohalide compound in a liquid carrier that includes a tissue penetrating agent for penetrating skin and the disordered tissue, the at least one organohalide compound comprising benzalkonium chloride having the following chemical structure:



wherein R is an alkyl group having 12, 14, 16, or 18 carbons (see claim 55).

As discussed above, Beauchamp et al. generally discloses quaternary ammonium halide compositions but fails to disclose or suggest the specific benzalkonium chloride compound recited in claim 71, which has been found to be particularly effective in killing viruses after only or two applications. For this reason alone, Applicant submits that claim 71 as amended is patentable over the applied art. Moreover, neither Beauchamp et al. nor Remington discloses or suggests any of the three application methods recited in claim 71 as amended.

New independent claim 72 alternatively claims a method for locally treating pathogen-induced disordered tissue caused by at least one of a virus, a bacteria, or a fungus, comprising: providing disordered tissue caused by a virus, bacteria or fungus; and applying a treatment composition to the disordered tissue in *one or more applications over a maximum period of about two minutes* (Application, page 45, lines 14-21) (30 seconds + 1 minute + 30 seconds = 2 minutes, and "30 seconds or longer" includes times of less than 2 minutes) so as to form a reservoir of the treatment composition within the disordered tissue and so that the treatment composition kills at least one of viruses, bacteria or fungus before diffusing beyond the disordered tissue. The treatment composition comprises at least one organohalide compound in a liquid carrier that includes a tissue penetrating agent for penetrating skin and the disordered tissue, the at least one organohalide compound comprising one or more of n-dialkyl methyl benzyl ammonium halide, n-alkyl dimethyl ethylbenzyl ammonium halide, a quaternary ammonium halide having an ammonium nitrogen and an alkyl radical with six to eighteen carbons bonded to the ammonium nitrogen, or benzalkonium chloride having the following chemical structure:



wherein R is an alkyl group having 8-18 carbons. The applied art fails to disclose or suggest the combination of elements recited in claim 72.

For example, Beauchamp et al. discloses a method in which the treatment composition is applied over a period of hours throughout the day (*see* col. 5, lines 55-65). Beauchamp et al. fails to disclose or suggest a method in which the treatment composition is applied "to the disordered tissue in one or more applications over a maximum period of about two minutes so as

to form a reservoir of the treatment composition within the disordered tissue and so that the treatment composition kills at least one of viruses, bacteria or fungus before diffusing beyond the disordered tissue". Nor does Remington suggest how one of skill in the art would modify the composition and method of Beauchamp et al. so as to meet the requirements of claim 72. Accordingly, for this reason alone, Applicant submits that claim 72 is patentable over the combination of Beauchamp et al. and Remington, either alone or in combination with any other art of record.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 15th day of January 2010.

Respectfully submitted,

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